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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,356	03/31/2004	Mark S. Zeiner	END5008USCIP2	8274

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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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09/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,356	Applicant(s) ZEINER ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-11,17,19 and 23-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-11,17,19 and 23-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/10/2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 6, 8-9, 17, 23-27, 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Haber** (U.S. Patent No. **5,385,552**).

Claims 1, 6, 8-9, 17, 23-27, 29-32: Haber discloses a trocar **2** with a hollow cannula **32** having a distal end and proximal end and a valve housing **58** attached to the proximal end of the cannula, wherein the proximal end has a wall attached thereto having an aperture therethrough, and an instrument seal assembly **122** disposed within said housing comprising a first substantially rigid ring **132**, and a second substantially

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rigid ring **134** and a plurality of layered elastomeric members, or four separate semicircular seal segments **126**, compressed therebetween, each having a circumference of 180 degrees, and arranged circumferentially about an aperture in an alternating over and under pattern in a non-planar shape (the elastomeric members also have a non-planar shape prior to being assembled together), and circumscribing an aperture in an interwoven pattern and cooperating to seal against objects positioned within the aperture, and each seal segment has a starting edge facing in the same circumferential direction and an ending edge facing in the opposite circumferential direction wherein the starting edge of each seal segment overlaps and is positioned on top of the ending edge of the adjacent seal segment, and the seal segments cooperate to seal against objects or instruments positioned within the aperture (Figures 2 and 5A).

Haber does not expressly disclose each seal segment **126** being gas-tight or sufficiently sealing against instruments positioned through the seal to maintain gas pressure in the abdominal cavity during endoscopic surgical procedures. However, it would have occurred to one of ordinary skill in the art to form a tighter seal that would further prevent fluid from escaping out the top end of the cannula whether an instrument is present in the cannula or not.

Haber discloses each seal segment having a circumference of 180 degrees but does not expressly disclose the segments having a circumference greater than 180 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made for the seal segments to have a circumference greater than 180 degrees, since it has been held that where the general conditions of a claim are

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disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

4. Claims 2-3, 10-11, 19, 28, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Haber** (U.S. Patent No. **5,385,552**), as applied to Claims 1, 9-10, 17 and 25 above, and further in view of **Honkanen** (U.S. Patent No. **4,655,752**).

Claims 2 and 10: Haber discloses the claimed device except for the plurality of layered elastomeric members forming a non-planar shape.

Honkanen teaches a cannula with a non-planar-shaped seal **55** (Figure 4). Honkanen teaches that the non-planar or conical shape assists in the formation of a tight seal about an instrument being inserted into the cannula since fluid pressure will cause the non-planar seal member to collapse into the instrument and cause it to adhere more securely thereto (col. 4, lines 53-58). It would have been obvious to one of ordinary skill in the art at the time of invention to provide non-planar-shaped elastomeric members, as taught by Honkanen, to Haber in order to facilitate a secure adhesion to the inserted instrument.

Claims 3, 11, and 19: Haber discloses the claimed device except for the elastomeric members comprising a proximal flange portion and an inwardly extending portion extending distally therefrom, wherein said proximal flange portions are disposed between and are abutting against said rings.

Honkanen teaches a proximal flange portion **56** and an inwardly extending portion **58**, wherein said proximal flange portions which would be disposed between and

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are abutting against the rings in the device of Haber (Figure 2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a proximal flange portion and an inwardly extending portion, as taught by Honkanen, to Haber since it was known in the art that seals with such portions are more securely mounted to the valve housing and more efficiently seal instruments that move through the valve.

Claims 28 and 33: Haber discloses the claimed device except for the seal further providing zero-closure seal.

Honkanen teaches the seal further providing zero-closure (Figure 5) and it would have been obvious to one of ordinary skill in the art to modify Haber by providing zero-closure, as taught by Honkanen, in order to form a tighter seal that would allow a snug fit about the instrument and to prevent fluid from escaping out the top end of the cannula (col. 4, lines 45-52).

5. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Haber** (U.S. Patent No. **5,385,552**) in view of **Hart** (U.S. Patent No. **5,385,553**)

Claim 4: Haber discloses the claimed device except for the seal assembly having an outer perimeter which is attached to a flotation means.

Hart teaches the seal assembly having an outer perimeter which is attached to a flotation means **39** that allows for movement of the septum orifice to an off-axis position without deformation (Figure 12, col. 2, lines 6-18 and col. 10, lines 41-63). It would have been obvious to one of ordinary skill in the art at the time of invention to modify

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Haber in providing a flotation means being attached to the outer perimeter of the seal assembly, as taught by Hart, in order to prevent deformation of the septum orifice.

Claim 5: Haber discloses the claimed device except for the seal assembly including a plurality of protectors disposed proximal to said elastomeric seal.

Hart teaches seal assembly including a plurality of protectors that comprises outer leaves **105, 107** and inner leaves **125, 127** disposed proximal to said elastomeric seal (Figures 9-10, col. 6, lines 48-68). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a plurality of protectors proximal to elastomeric seal, as taught by Hart, to Haber in order to shield the sealing members from the pushing force of the instruments.

Response to Arguments

6. Applicant's arguments filed 08/10/2009 have been fully considered but they are not persuasive.

7. Applicant generally argues that Haber's sealing elements 124 seal the path of the device only when an instrument is not positioned along the path, and therefore it would not be obvious to modify these seal elements to provide a gas-tight seal around an instrument since another element 136 provides that function in the device. The examiner disagrees. As seen in figure 3A of Haber, when an instrument 14 is passed through the path, sealing elements 124 appear to provide a seal around the instrument (in between elements 132 and 134) much like the other sealing element 136. It would have been obvious to one of ordinary skill in the art to modify the sealing elements 124

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of Haber to further seal the path whether or not there is an instrument present in the path or not, since it was old and well known in the art to make a sealing mechanism tighter to maintain an effective closure mechanism.

8. In addition, applicant generally argues that the sealing elements 124 are not arranged about an aperture because doing so would provide a direct leak path and is contrary to the teachings of Haber. However, the recitation of the claim only necessitates that the sealing elements 124 are “arranged about an aperture” and do not necessarily form an aperture in their cooperative sealing configuration. Therefore, as seen in Figure 2 of Haber, for example, the sealing elements may be considered to be arranged about or disposed around any apertures of the device, including those of elements 134, 136, 118, or 102, and therefore reads on this limitation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
8/29/09